UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Human Health, and Ecological Risk Assessment for a FIFRA Section 3 Registration of the Manufacturing-Use Product Sucrose Octanoate Esters (α-D-Glucopyranosyl - β-D-fructofuranosyl - octanoate) and the End-Use Product, Organoshield containing 40% Sucrose Octanoate Esters

Decision Number:	559307, 559311
DP Number:	456478, 456483
Submission Number:	1045262, 1045263
EPA File Symbol Number:	94224-R (EP), 94224-E (MP)
Chemical Class:	Biochemical
PC Code:	035300
CAS Numbers:	42922-74-7, 58064-47-4
MRID Numbers:	50982501-03, 51031601-03
PRIA Code:	B612

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ACTION REQUESTED

On behalf of PHD Group LLC, IR-4 requests registration of a product with an existing tolerance exemption. The proposed end-use product (EP) is intended for use on a) various crops to control soft-bodied insects and mites, b) mushroom growing media to control sciarid flies, and c) adult honey bees to control Varroa mites. In support of the registration, the applicant submitted a proposed product label, Confidential Statements of Formula (CSF) dated 04-28-2020, a data matrix dated 01-02-2020 and product chemistry, human health assessment and nontarget organism toxicity data and information.

INTRODUCTION AND BACKGROUND

The Avachem Sucrose Octanoate Manufacturing-Use Product was originally registered as 70950-1 and the EP, Avachem Sucrose Octanoate (40%) was registered as 75197-1, however both registrations were cancelled due to non-payment of the Pesticide Maintenance Fee in 2005 and 2017, respectively. The Organoshield Sucrose Octanoate Manufacturing-Use Product (MP) and EP, Organoshield Sucrose Octanoate Esters (40%) submitted for registration are identical to the previously registered MP (Reg No. 70950-1) and EP (Reg No. 75197-1). That is, each MP consists of 85.43% sucrose octanoate esters [(α-D-glucopyranosyl- β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] made from a caprylic fatty acid ester derived from an edible oil or fat, and sucrose, a sugar which is a regular part of the diet of humans and animals. Both EPs consist of 40% sucrose octanoate esters and the same inert ingredient composition. The vendor for the active ingredient in the new MP (Applied Power Concepts) is the same vendor used in the previous registration. The inert ingredient was sourced from a different vendor however, a Safety Data Sheet was provided for the updated vendor which, demonstrated no difference in hazard from the previous source.

Although sucrose octanoate esters has been submitted for registration in new MP and EP products, it has been previously assessed by the Agency for earlier registration actions. The mode of action for sucrose octanoate esters is physical and non-toxic; the surfactant effect of sucrose octanoate esters de-waxes the cuticle of the target pest, causing it to desiccate. All data requirements have been satisfied except for those addressing the inhalation exposure pathway. No risks of concern have been identified for sucrose octanoate esters; however, a risk conclusion cannot be made regarding inhalation exposure since no acute or subchronic inhalation data are available. Because inhalation toxicity remains a data gap, the Agency recommends adding a respirator to the PPE label requirements to mitigate any potential risk posed by inhaling sucrose octanoate esters.

1. Biopesticide Use Pattern

Organoshield Sucrose Octanoate Esters [40.0%] is biochemical insecticide/miticide applied as a liquid spray for field, greenhouse, and nursery use on any type of agricultural commodity (including certain nonfood ornamentals); as well as on mushroom growing media and on adult honey bees. Most conventional ground spray application equipment may be used. The proposed EP label specifies application rates a) between 0.8% and 1.0% volume/volume (v/v) for foliarly applied spray, b) between 1.25% and 2.50% v/v for mushroom growing media, and c) of 0.625% v/v for application to honey bees.

3. Human Health Risk Assessment

A. Active Ingredient/ Manufacturing-Use Product

Tier I toxicology data (acute toxicity, subchronic toxicity, developmental toxicity and genotoxicity) are required for TGAIs. To satisfy these data requirements, PHD Group, LLC submitted MRID 50982502 which, cited data and waiver rationales submitted for previous registration actions (Table 3). In addition, two new studies from the peer-reviewed literature were provided as supplemental information to support the human health toxicology risk assessment (Takeda and Flood, 2002; Yoshida et al., 2004; MRID 50982502), however no new DERs were created, since reviews of the cited data are contained in USEPA 2000, 2001, 2002a,b,c and new data were presented in peer-reviewed literature. All human health assessment data requirements for the MP have been satisfied with the exception of acute and subchronic inhalation toxicity.

B. End-Use Product

Acute toxicity data are required for EPs. To satisfy these data requirements, PHD Group, LLC submitted MRID 51031602 which, cited data and waiver requests submitted for previous registration actions (Table 3). In addition, two studies from the peer-reviewed literature were provided as supplemental information to support the human health toxicology risk assessment (Takeda and Flood, 2002; Yoshida et al., 2004; MRID 51031602), however no new DERs were created, since reviews of the cited data are contained in USEPA 2000, 2001, 2002a,b,c and new data were presented in peer-reviewed literature. All human health assessment data requirements for the EP have been satisfied with the exception of acute inhalation toxicity.

Table 3. Summary of Human Health Assessment Data for Octanoate Esters

Guideline and Data Requirement	**Result for Sucrose Octanoate Esters TGAI/MP**	**Result for Sucrose Octanoate Esters EP**	**MRID MP/EP**
870.1100: Acute oral Toxicity	Toxicity Category IV LD50 <20,000 mg/kg	Data waiver granted Toxicity Category IV	44415803 and Amendment No. 1 Takeda and Flood, 2002; Yoshida et al., 2004; MRIDs 50982502 and 51031602
870.1200: Acute Dermal Toxicity	Data waiver granted Toxicity Category IV	Data waiver granted Toxicity Category IV	44415803 Amendment No. 1, and 44415804
870.1300: Acute Inhalation Toxicity	Data gap	Data gap	None
870.2400: Primary eye irritation	Tox Category I Moderate to severe eye irritation and mild corneal opacity in all rabbits at 24 hours post-dosing and persisted in one rabbit to 21 days post-dosing. Mild iritis was exhibited in 3 rabbits at 24-hours post-dosing and persisted in one to 72 hours.	Tox Category II Moderate to severe eye irritation was observed in all 6 rabbits at 72 hours post-dosing, was mild at 7days, and cleared by 14 days. Mild corneal opacity was observed in all 6 rabbits at 24 hours, and persisted to seven days in one rabbit.	44610105 44610106
870.2500: Primary Dermal Irritation in Rabbits	Toxicity Category IV 5 rabbits exhibited very slight erythema and one exhibited well-defined erythema at one-hour posttreatment. Very slight erythema persisted on four rabbits to 24 hours, then cleared.	Toxicity Category IV Very slight erythema was exhibited by six rabbits at 0.5-hour post-treatment and five rabbits exhibited very slight to slight edema. All symptoms cleared by 24 hours.	44610103 44610104
870.2600: Dermal Sensitization	Non-sensitizing	Non-sensitizing	Scott, 2017
870.3100: 90-Day Oral Toxicity	Data waiver granted- Low acute toxicity; Normal presence in human diet; No history of adverse effects	Data waiver granted- Low acute toxicity; Normal presence in human diet; No history of adverse effects	None Takeda and Flood, 2002; Yoshida et al., 2004; MRIDs 50982502 and 51031602
870.3250: 90-Day Dermal Toxicity	Data waiver granted- Low acute toxicity; Normal presence in human diet; No history of adverse effects	Data waiver granted- Low acute toxicity; Normal presence in human diet; No history of adverse effects	44415803
870.3465: 90-Day Inhalation Toxicity	Data gap	Data gap	None
870.5300: Genotoxicity	Data waiver granted	Data waiver granted	None
870.5100: Mutagenicity	Data waiver granted	Data waiver granted	None

Guideline and Data Requirement	**Result for Sucrose Octanoate Esters TGAI/MP**	**Result for Sucrose Octanoate Esters EP**	**MRID MP/EP**
870.3700: Teratogenicity	Data waiver granted	Data waiver granted	None

None: No MRID was created for this waiver request

C. Acute Toxicity

For the previous registration of sucrose octanoate esters MP and EP, Avachem submitted guideline studies and acceptable data and information from the open technical literature (Table 3.) to satisfy the requirement for acute oral and dermal toxicity studies, as well as for primary eye irritation. Based on the submitted information and additional relevant data found by the Agency from public sources, including the National Toxicology Program (USEPA, 2002c), BPPD categorized both the MP and EP sucrose octanoate esters products as Toxicity Category IV for acute oral toxicity and acute dermal toxicity. Guideline primary eye irritation and primary dermal irritation studies were submitted to support the MP and EP. The MP is considered moderately to severely irritating to the eyes (Toxicity Category I) and slightly irritating to the skin (Toxicity Category IV). The EP is considered moderately to severely irritating to the eyes (Toxicity Category II) and slightly irritating to the skin (Toxicity Category IV).

Guideline studies nor data from the open literature were available for skin sensitization, however, analogues of sucrose octanoate esters are widely used in cosmetics as emollients, skin conditioning-agents, fragrance ingredients, and emulsion stabilizers. The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) reviewed the relevant data for saccharide esters and concluded those evaluated indicated that saccharide esters are non-sensitizing (Scott, 2017). Based on review of the animal model data included in the CIR safety assessment for saccharide esters, the Agency concludes low to no risk for sucrose octanoate esters as a skin sensitizer.

Guideline studies nor data from the open literature were available for acute inhalation. The lack of acute inhalation studies for sucrose octanoate esters represents an important data gap because the MP is a Toxicity Category I primary eye irritant, which suggests that it may be a portal-of-entry irritant. In addition, the EP is applied as a spray, therefore applicator inhalation exposure is possible. Acute risk from inhalation of sucrose octanoate esters is uncertain.

D. Genotoxicity and Mutagenicity

No guideline studies were submitted, but the Agency determined none are required because published information from the open, technical literature was cited to scientifically justify waivers for these studies (MRID 44415803 and Amendment No. 1). The submitted data and information demonstrate that sucrose octanoate esters are not genotoxic and/or mutagenic, nor structurally and/or chemically similar to known mutagens or known classes of mutagens (USEPA, 2000). A study reported by the NTP shows a sucrose octanoate esters constituent as well as octanoic acid to be negative for genotoxicity/mutagenicity (USEPA 2002c).

E. 90-Day Oral Toxicity, 90-Day Dermal Toxicity, 90-Day Inhalation Toxicity and Developmental Toxicity

Due to the low toxicity of sucrose octanoate esters (as demonstrated in the cited open technical literature within MRID 44415803 and Amendment No. 1, USEPA, 2000, USEPA 2002a&b), the Agency granted waivers from the 90-day oral toxicity and developmental studies. In addition, a sucrose octanoate esters constituent as well octanoic acid are considered a non-teratogenic compound even at the very high dose

rate of 18.75 mmoles/kg (USEPA, 2002c). The 90-day dermal study was also waived since there was no indication of systemic toxicity via dermal exposure in the acute study and no dermal irritation (Toxicity Category IV; MRID 44415803). In addition, dermal exposure is expected to be limited as a result of personal protective equipment (PPE) requirements on the label (i.e. long-sleeved shirt and long pants, shoes plus socks, and protective eyewear).

In December 2009, the agency sought expert advice and input from its FIFRA Scientific Advisory Panel (SAP) on issues related to this route-to-route extrapolation approach in the absence of an inhalation toxicity study (i.e., the use of oral toxicity studies for inhalation risk assessment). Based on the SAP's recommendations in the March 2, 2010 Final Report, the agency has increased its focus on the uncertainties associated with route-to-route extrapolation and is presently considering the need for inhalation toxicity studies more frequently. The current review finds short- and intermediate-term inhalation risk for sucrose octanoate esters to be uncertain for the following reasons:

- There was no data submitted for acute inhalation toxicity.
- PPE label requirements for the EP do not include a respirator which, would preclude inhalation exposure of aerosolized sucrose octanoate.
- The fact that the MP is a Toxicity Category I primary eye irritant suggests that it may be a portal-of-entry irritant.

Based on the use pattern and application methods there is potential for applicator inhalation exposure via spraying of the product. Short- and intermediate-term inhalation risk from exposure to sucrose octanoate esters is uncertain.

F. Additional Data Cited from the Peer-Reviewed Literature

Takeda and Flood (2000) conducted a 13-week and a two-year study to evaluate the oral toxicity and carcinogenicity of S-570, a mixture of mono-, di-, tri-, and higher esters of sucrose fatty acids derived from edible fats and oils, to rats. There were no S-570-related effects on survival, tumor incidence or time to tumor, ophthalmology, hematology, clinical chemistry, organ weights, or histopathology. Authors concluded that results indicate that S-570 is not toxic or carcinogenic when fed to rats up to 5% of the diet for two years. Yoshida et al (2003) also conducted a chronic combined toxicity and carcinogenicity study in which sucrose fatty acids were fed to rats. In the 12-month chronic toxicity study, no treatment-related effects on body weights, or hematological, blood biochemical, urinary and pathological parameters were demonstrated in any of the treated groups. In the carcinogenicity study, S-170 did not cause any dose-related significant increase in the incidences of tumors in any organs or tissues. The authors concluded that, taken together, the results demonstrate that S-170 has neither toxic nor carcinogenic activity in F344 rats under the conditions of the study. These studies are considered **ACCEPTABLE** for use in the human health risk assessment.

G. Dietary exposure and RiskCharacterization

An exemption from the requirement of a tolerance is established for residues of sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] in or on all food commodities when used in accordance with good agricultural practices. [67 FR 60152, Sept. 25, 2002]. Dietary (food and drinking water) exposures and risk assessments were not conducted based on the lack of toxicity of octanoate esters. Any potential pesticidal residues of octanoate esters in drinking water are anticipated to be negligible and continued use of octanoate esters as a pesticide does not present any concern to the Agency. Risk from dietary or drinking water exposure to sucrose octanoate esters is not expected.

H. Residential Exposure and Risk Characterization

There are no proposed residential (non-occupational) uses associated with sucrose octanoate esters therefore, a residential handler and post-application exposure and risk assessment has not been conducted.

I. Occupational Exposure and Risk Characterization

There is a potential for occupational exposure to octanoate esters. BPPD concluded that the submitted acute dermal toxicity information indicated no toxicity or irritation (Toxicity Category IV; MRID 44415803). In addition, there was no indication of systemic toxicity via dermal exposure in the acute study and dermal exposure is expected to be limited as a result of personal protective equipment (PPE) requirements on the label (i.e. long-sleeved shirt and long pants, shoes plus socks, and protective eyewear). Furthermore, BPPD has concluded that sucrose octanoate esters are not skin sensitizers. Based on these results, the anticipated risks from dermal exposure for handlers are considered minimal.

The Organoshield Sucrose Octanoate Esters (40%) label contains a hazard statement warning that the product causes substantial but temporary eye injury. Risks to eyes can be prevented by the use of required protective eyewear (goggles or face shield). The EP falls under the provisions of the Worker Protection Standards, therefore PPE (long-sleeved shirt and long pants, shoes plus socks, and protective eyewear) and restricted-entry interval of 48-hours is required. As discussed previously, acute and subchronic inhalation risk is uncertain due to the lack of data; the fact that the MP is a Toxicity Category I eye irritant, the EP is applied as a spray, and because the proposed label does not require use of a respirator.

V. Aggregate Exposure and Risk Characterization

In accordance with the FQPA, BPPD must consider and aggregate pesticide exposures and risks from three major sources; food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard [e.g., a NOAEL or population-adjusted dose (PAD)], or the risk themselves can be aggregated. When aggregating exposures and risks from various sources, BPPD considers both the route and duration of exposure.

As anticipated dietary (food and drinking water) and bystander exposures are expected to be negligible and sucrose octanoate esters are considered to be of low toxicity, aggregate exposure and risk is anticipated to be negligible.

VI. Cumulative Exposure and Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sucrose octanoate esters and any other substances and this biopesticide does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that sucrose octanoate esters has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides).

4. Nontarget Organism Risk Assessment

A. Active Ingredient

Tier I nontarget organism toxicity data avian (oral and dietary), freshwater fish, freshwater aquatic invertebrate, terrestrial plant (seedling emergence and vegetative vigor), and nontarget insect toxicity testing are required for TGAIs. To satisfy these data requirements, PHD Group, LLC submitted MRID 50982503 which, cited waiver requests submitted for previous registration actions for sucrose octanoate esters, as shown in Table 4. For the current application, a new study was submitted from the peer-reviewed literature to support the avian acute toxicity and dietary data requirements (MRID 50982503; Tupper et al., 2014). The non-target insect data requirement was previously satisfied via the submission of an acute contact honey bee toxicity study from which the Agency determined that the active ingredient may be classified as practically non-toxic to honey bees (LD_{50} > 80 µg active ingredient/bee, MRID 45197403). The submission of three supplemental nontarget insect studies obtained from the open technical literature indicate that sucrose octanoate esters are relatively non-toxic to certain non-target, beneficial insects (USEPA, 2000). Two studies were submitted in MRID 50982503 for the current registration which also satisfy the non-target insect data requirement.

Acceptable information/data were submitted from the open technical literature to support the data requirements for avian acute oral toxicity, avian dietary toxicity, freshwater fish acute toxicity, freshwater invertebrate acute toxicity, non-target plants, and non-target insects. No new DERs were prepared for the current review, since reviews of the cited data are contained in USEPA 2000, 2001, 2002a,b,c and new data were presented in peer-reviewed literature.

B. End-Use Product

Nontarget organism data are typically not required for biochemical pesticide EPs, unless triggered based on a concern for toxicity from an inert ingredient. There are no inerts with toxicity concerns in the EP, therefore non-target organism toxicity data are not required. PHD Group LLC submitted MRID 51031603 which, cited waiver requests submitted for previous registration actions for sucrose octanoate esters, as shown in Table 4.

Table 4. Summary of Nontarget Organism Data for Octanoate Esters

Guideline and Data Requirement	Result	MRID or Other Source
850.2100: Avian Acute Oral Toxicity	Data waiver granted-Degrades rapidly in environment; Low acute toxicity; lack of toxicity in the submitted supplemental nontarget studies; No history of adverse effects	44415805 (waiver) U.S EPA, 2000 (review) 50982503, 51031603 (Tupper et al., 2014)
850.2200: Avian Dietary Toxicity	Data waiver granted-Degrades rapidly in environment; Low acute toxicity; lack of toxicity in the submitted supplemental nontarget studies; No history of adverse effects	44415805 (waiver) U.S EPA, 2000 (review) 50982503, 51031603 (Tupper et al., 2014)
850.1075: Fish Acute Toxicity, Freshwater	Data waiver granted-Degrades rapidly in environment; Low acute toxicity; lack of toxicity in the submitted supplemental nontarget	44415805 (waiver) U.S EPA, 2000 (review)

Guideline and Data Requirement	Result	MRID or Other Source
	studies; No history of adverse effects	
850.1010: Aquatic Invertebrate Acute Toxicity, Freshwater	Data waiver granted-Degrades rapidly in environment; Low acute toxicity; lack of toxicity in the submitted supplemental nontarget studies; No history of adverse effects	44415805 (waiver) U.S EPA, 2000 (review)
850.4100: Terrestrial Plant Toxicity, Seedling Emergence	Data waiver granted-Degrades rapidly in environment; Low acute toxicity; lack of toxicity in the submitted supplemental nontarget studies; No history of adverse effects	44415805 (waiver) U.S EPA, 2000 (review)
850.4150: Terrestrial Plant Toxicity, Vegetative Vigor	Data waiver granted-Degrades rapidly in environment; Low acute toxicity; lack of toxicity in the submitted supplemental nontarget studies; No history of adverse effects	44415805 (waiver) U.S EPA, 2000 (review)
880.4350: Nontarget Insect Testing	Lack of toxicity in the submitted supplemental nontarget studies (LD50> 80 µg/ai/bee); No history of adverse effects, lack of toxicity in studies submitted from the primary literature.	44415805 45197403 (honey bee study) U.S EPA, 2000 (review) 50982503, 51031603 (McKenzie., 2004; Michaud and McKenzie, 2004)

C. Additional Non-Target Organism Studies Cited from the Peer-Reviewed Literature

New study to support waiver rationale for avian toxicity testing

In support of the registration application a study was submitted which, evaluated the laboratory efficacy of SucraShield™ which, contains 40% sucrose octanoate esters, as a chemical repellent for European starlings (MRID 50982503; Tupper et al., 2014). The study found that SucraShield™ was not an effective repellent for starlings and in fact increased consumption of CU Bird Carrier as concentration increased. Benzenberg (2019) stated in MRID 50982503 that birds in this study that were fed a diet containing sucrose octanoate demonstrated no ill effects. This statement is not supported by the data in the study since there was no discussion of adverse effects in the study. As a result, uncertainty remains regarding whether or not adverse effects were documented as a part of the study methodology, therefore this study is classified as **SUPPLEMENTA**L for use in the risk assessment.

New studies submitted to support waiver rationale for non-target insects

Two new studies were submitted to support the waiver rationale for non-target insects. In one study, Michaud and McKenzie (2004) found sucrose octanoate to be non-toxic to the following beneficial insects representing four orders important in biological control of homopteran pests: *Aphytis melinus* De Bach (Hymenoptera: Aphelinidae); green lacewing, *Chrysoperla rufilabris* Burmeister (Neuroptera: Chrysopidae); insidious flowerbug, *Orius insidiosus* (Say) (Hemiptera :Anthocoridae); and four species of ladybeetles, i.e., *Curinus coeruleus* Mulsant, *Cycloneda sanguinea* L., *Harmonia axyridis* Pallas, and *Olla v-nigrum* Mulsant (Coleoptera: Coccinellidae). McKenzie (2004) examined the toxicological effects of sucrose octanoate esters on brown citrus aphid, *Toxoptera citricida* (Kirkaldy), nymphs and adults and

to its native parasitoid *Lysiphlebus testaceipes* (Cresson). They concluded that sucrose octanoate is selectively active against homopteran pests yet is nontoxic to the beneficial insects occupying the same environment and should provide an alternative insecticide for citrus growers that allow them to preserve the natural beneficial complex in their grove. These studies were found to be **ACCEPTABLE** for use in the risk assessment.

D. Exposure and Risk Characterization

Sucrose octanoate does not persist in the environment and biodegrades quickly. The TGAI degrades within approximately five days at approximately 20-27˚C, in both aerobic and anaerobic conditions. When applied according to the proposed label directions, no direct significant exposure of birds or aquatic organisms to octanoate esters is expected to occur. Based on the lack of toxicity (submitted supplemental nontarget insect studies, MRIDs 44415805 and 50982503; USEPA, 2000) and the fact the octanoate esters degrades rapidly in the environment, the Agency concludes that it is unlikely that any toxic effects will occur in birds, freshwater fish, freshwater aquatic invertebrates, non-target plants or non-target insects when the product containing sucrose octanoate esters is used according to label instructions.

VII. Risk to Federally Listed Threatened and Endangered Species

Since EPA has determined that no effects are anticipated for any non-target species exposed to sucrose octanoate esters as a result of the proposed labeled applications, effects to federally listed threatened and endangered ('listed') species and their designated critical habitats are also not expected. Therefore, a "No Effect" determination is made for direct and indirect effects to listed species and their designated critical habitats resulting from the proposed uses of sucrose octanoate esters, as labeled.

CONCLUSIONS AND RECOMMENDATIONS

- No unreasonable adverse effects on the environment are anticipated from exposure to Sucrose Octanoate MP or Organoshield Sucrose Octanoate Esters (40%) when used in accordance with the proposed label.
- No unreasonable adverse effects on humans are anticipated from oral, dermal, or ocular exposure to Sucrose Octanoate MP or Organoshield Sucrose Octanoate Esters (40%) when used in accordance with the proposed label.
- Due to the uncertainty regarding inhalation toxicity, PPE label requirements for application should include a respirator to mitigate exposure to sucrose octanoate esters or else acute and subchronic inhalation studies or waiver rationales should be submitted.
- The droplet size classification on the label should be updated from ASAE 572 to reflect the most current classification as outlined in ASABE S572.1.
- Future data submissions for registration should separate new data and studies from citations of older MRIDs. For example, the new peer-reviewed literature articles should have their own MRIDs separate from citations of existing MRIDs.

BIBLIOGRAPHY OF REVIEWS AND STUDIES

Citations

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USEPA, February 14, 2000. Science review in support of registration of sucrose octanoate esters. R. S. Jones to D. Greenway.

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USEPA, 2002b. Sucrose Octanoate Esters; a Request for Concurrence on a Decision to Waive the Requirement for 90-Day Feeding (152-20) and Teratogenicity (152-23) Studies, Based on the Registrant's Correspondence of July 12, 2002. D. Greenway to R.S. Jones; August 7, 2002.

USEPA; August 8, 2002c. Brief Summary of Toxicity Information to Support Registration/Tolerance Exemptions for Sucrose Octanoate. R. S. Jones to D. Greenway.

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Yoshida, M., Katsuda, S.I., Nakae, D. and Maekawa, A., 2004. Lack of toxicity or carcinogenicity of S-170, a sucrose fatty acid ester, in F344 rats. Food and chemical toxicology. 42(4):667-676.

List of MRIDs for Studies Supporting the Registration of Sucrose Octanoate Esters

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45197402	Barrington, T. (2000) Sucrose Fatty Acid Esters-Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties Amendment No. 1 to MRID No. 44415802: Lab Project Number: IR-4 PR NO. 89B. Unpublished study prepared by AVA Chemical Venture, L.L.C. 107 p.	25-Aug-2000
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